

David E. De Lorenzi  
Christopher H. Strate  
**GIBBONS P.C.**  
One Gateway Center  
Newark, New Jersey 07102-5310  
(T) (973) 596-4500  
(F) (973) 639-6492

*Attorneys for Plaintiff  
The Medicines Company*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

THE MEDICINES COMPANY,

Plaintiff,

v.

EAGLE PHARMACEUTICALS, INC.;  
SCIDOSE LLC; and THERDOSE  
PHARMA PVT. LTD.,

Defendants.

Civil Action No.: 16-cv-\_\_\_\_\_

**COMPLAINT**

Plaintiff, The Medicines Company ("The Medicines Company"), by and through its counsel, Gibbons P.C., as and for its Complaint against Defendants Eagle Pharmaceuticals, Inc. ("Eagle"), SciDose LLC ("SciDose") and TherDose Pharma Pvt. Ltd. ("TherDose") (collectively, "Defendants"), alleges as follows:

**SUMMARY OF ACTION**

This is an action for patent infringement, declaratory judgment of ownership of patent rights misappropriated by Defendants, and injunctive and other equitable relief designed to rightfully return intellectual property belonging to The Medicines Company and to enjoin Defendants from wrongfully infringing The Medicines Company's intellectual property.

The Medicines Company is a leading provider of pharmaceuticals for the acute care, hospital-based market, including its leading anticoagulant product, Angiomax®. Angiomax® is a direct thrombin inhibitor which is indicated for, *inter alia*, use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty. Over time, it has grown to be the anticoagulant market leader in angioplasties. Angiomax® is covered by several United States ("US") patents, many of which are asserted in this action.

Eagle currently promotes itself as a "specialty pharmaceutical company focused on developing injectable products." TherDose and SciDose are affiliates of Eagle. They serve as Eagle's technical/scientific support team. For all intents and purposes of this action, Eagle, TherDose, and SciDose are largely one in the same.

The Medicines Company and Defendants are no strangers to each other. The Medicines Company engaged -- and paid handsomely -- Defendants to develop a ready-to-use liquid formulation of Angiomax®, otherwise known as an "RTU" formulation (hereinafter the "Development Agreement"). The Medicines Company did so based upon Defendants' then claimed expertise in developing RTU formulations. Naturally, in doing so, The Medicines Company shared its highly sensitive information concerning Angiomax® in confidence with Defendants.

The Medicines Company's Development Agreement with Defendants made clear that any patents or patent applications arising from the development program would be jointly owned by The Medicines Company and Eagle. The Development Agreement also made clear that The Medicines Company would be the exclusive licensee of any such patents or patent applications, even to the exclusion of Defendants. Further, under the Development Agreement, The

Medicines Company alone would determine what patent applications, if any, would be filed. Naturally, at least during the term of the Development Agreement, Defendants were prohibited from doing any other development work around bivalirudin except on behalf of The Medicines Company.

During the development program, two US patents ultimately issued based upon the program work. Each of these patents were jointly assigned to The Medicines Company and Eagle jointly and, in turn, licensed exclusively to The Medicines Company.

On the commercial side, however, Defendants were long on promises and short on delivery. To The Medicines Company's disappointment, Defendants failed to develop an RTU bivalirudin product that met The Medicines Company's expectations. Moreover, when The Medicines Company challenged Eagle on its failures, Eagle's only response was to finger-point at The Medicines Company. And then, when that did not work out as Eagle planned, Eagle abruptly declared that it was "terminating" the Development Agreement.

As it turns out, Eagle's purported "termination" was just a ruse to conceal Defendants' plan to misappropriate for themselves the RTU bivalirudin development program intellectual property and pursue its own patent application for RTU bivalirudin in hopes of launching an RTU bivalirudin product to compete directly with Angiomax®. For Eagle, timing was critical. Eagle knew that as long as the Development Agreement was in effect, 1) Eagle was prohibited from developing an RTU bivalirudin product other than for The Medicines Company; and 2) anything conceived or developed by Eagle around bivalirudin could only be exploited by The Medicines Company. Thus, Eagle had to create the illusion of time after Eagle's purported

“termination” to claim that Eagle had not misappropriated The Medicines Company’s rights in RTU bivalirudin.

Eagle's illusion, however, has been unveiled. For example, The Medicines Company has learned that, within just several weeks after Eagle declared its purported “termination” of the development program, Eagle requested and conducted a meeting with the FDA regarding its RTU bivalirudin product and completed registration batches shortly thereafter -- implausible timeframes for truly new drug formulation development work by any standard. During the same time period, upon information and belief, Eagle filed a patent application directed to RTU bivalirudin technology based on development program intellectual property (the “new RTU patent application”) -- again an incredible “strike of genius” only mere months after Eagle purported to “terminate” its development program with The Medicines Company. Less cautiously (or more brazenly perhaps), Eagle publicly acknowledged that its RTU bivalirudin product “was originally subject of a licensing agreement with The Medicines Company” -- a stunning admission that quickly dispels any doubt regarding the true ownership of the new RTU patent application and product, and thus any doubt regarding Eagle's substantial exposure in this lawsuit.

The issue has now been joined. Eagle's new RTU patent application published on November 19, 2015. (U.S. Application No. 14/711,359). This patent application confirms MDCO's suspicions that Eagle's purported "new RTU product" and Eagle's claimed "invention" are not new at all, but merely relate back to work done during the MDCO/Eagle development program. Thus, each are owned by and licensed exclusively to MDCO. Eagle has publicly touted that its new RTU patent application covers Eagle's claimed "new" RTU product.

Second, Eagle has delivered to The Medicines Company a letter ("Notice Letter") advising that Eagle has filed a New Drug Application ("505(b)(2) NDA") No. 208298 seeking approval to commercialize an RTU bivalirudin product with the Food and Drug Administration ("FDA") under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"). Notably, Eagle's Notice Letter does not certify that its RTU bivalirudin product would not infringe the two RTU bivalirudin development program patents licensed exclusively to The Medicines Company and asserted in this action.

Further, Eagle has now advised The Medicines Company that Eagle's 505(b)(2) NDA has a PDUFA action date of March 19, 2016 and that "Eagle's current intention is to promptly launch that product upon approval." Moreover, taking its brazenness to even new heights, Eagle has now requested The Medicines Company to provide it with a covenant not to sue Eagle for any claims under the Development Agreement regarding Eagle's "new" RTU product -- a clear acknowledgment by Eagle that, notwithstanding its purported "termination" of the Development Agreement and its ensuing "new patent/new product" charade, any attempt by Eagle to sell its RTU product would expose Eagle to substantial liability under the License. Thus, Eagle's more recent covenant not to sue request is just the next (and, for The Medicines Company, final) chapter in Eagle's "new" RTU charade.

Relatedly, ownership in the new RTU patent application is disputed, and therefore, under the Development Agreement, ownership of those patent rights can be resolved by this Court.

Accordingly, The Medicines Company is now forced to bring this action seeking, *inter alia*, a judgment that Eagle has and will continue to infringe The Medicines Company's patent rights; a declaration of The Medicines Company's ownership and exclusive license rights in the

new RTU patent application; and injunctive relief barring Defendants from marketing as its own and/or exploiting The Medicines Company's patent rights to unfairly compete with The Medicines Company.

### **NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 7,713,928 ("the '928 patent") (attached as Exhibit A), and 7,803,762 ("the '762 patent") (attached as Exhibit B).

2. This is also an action for declaratory judgments of ownership in certain patent rights, breach of contract, conversion, misappropriation, unjust enrichment and constructive trust.

### **THE PARTIES**

3. Plaintiff The Medicines Company, at all times relevant to this action, was and is a corporation organized and existing under Delaware law, with its principal place of business located at 8 Sylvan Way, Parsippany, New Jersey 07054.

4. Upon information and belief, at all times relevant to this action, Defendant Eagle was and is a corporation organized and existing under Delaware law, with its principal place of business located at 470 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

5. Upon information and belief, at all times relevant to this action, Defendant SciDose was and is a corporation organized and existing under Massachusetts law, with its principal place of business located at 123 Blackberry Lane, Amherst, Massachusetts 01002.

6. Upon information and belief, at all times relevant to this action, Defendant TherDose was and is a limited liability company established under the laws of India, with its principal place of business located at Plot: 30-32, 1<sup>st</sup> Floor, Prashanth Nagar Industrial Estate, Kukatpally, Hyderabad-500 072, AP, India. Upon information and belief, Defendant TherDose is a subsidiary of and controlled by Defendant SciDose.

7. As Eagle's technical/scientific arm, upon information and belief, SciDose and/or Therdose knowingly participated in, directed and/or conspired with Eagle throughout the events and actions alleged herein, including participating in the development of RTU bivalirudin technology during the course of the development program between the parties.

#### **JURISDICTION AND VENUE**

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1367.

9. This Court has personal jurisdiction over the Defendants.

10. This Court has jurisdiction over Eagle by virtue of, *inter alia*, Eagle's principal place of business being located in New Jersey and Eagle's continuous and systematic contacts with New Jersey, including its contractual relationships with parties in New Jersey, such as, The Medicines Company. The Court also has specific jurisdiction over Eagle because this action "arises out of" and "relates to" Eagle's contacts with The Medicines Company, a New Jersey company, relative to the dispute at issue.

11. This Court has jurisdiction over SciDose by virtue of, *inter alia*, SciDose's continuous and systematic contacts with New Jersey, including its contractual relationships with

parties in New Jersey, such as, The Medicines Company and Eagle. The Court also has specific jurisdiction over SciDose because this action “arises out of” and “relates to” SciDose’s contacts with The Medicines Company and Eagle, New Jersey companies, relative to the dispute at issue.

12. This Court has jurisdiction over TherDose by virtue of, *inter alia*, TherDose’s continuous and systematic contacts with New Jersey, including its contractual relationships with parties in New Jersey, such as, The Medicines Company and Eagle. The Court also has specific jurisdiction over TherDose because this action “arises out of” and “relates to” TherDose’s contacts with The Medicines Company and Eagle, New Jersey companies, relative to the dispute at issue.

13. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c), and § 1400(b).

14. Upon information and belief, Defendants: (i) operate a permanent business location within this judicial district and can, therefore, be found in this judicial district and are residents of this judicial district; and/or (ii) on information and belief, substantial events giving rise to acts of infringement have occurred and/or will occur within this judicial district, including but not limited to the preparation of and/or contribution to the submission and/or filing of Eagle’s 505(b)(2) NDA under section 505(b)(2) of the FDCA (codified at 21 U.S.C. § 355(b)) seeking approval to market a bivalirudin drug product that infringes the ‘928 and/or ‘762 patents.

### **THE PATENTS**

15. The ‘928 patent, entitled “Ready-To-Use Bivalirudin Compositions,” was duly and legally issued on May 11, 2010, to The Medicines Company and Eagle upon assignment from



Nagesh Palepu, Rajeshwar Motheram, Praful Shah and Gopal Krishna. The '928 patent is generally directed to RTU bivalirudin compositions.

16. The '762 patent, entitled "Ready-To-Use Bivalirudin Compositions," was duly and legally issued on September 28, 2010, to The Medicines Company and Eagle upon assignment from Nagesh Palepu, Rajeshwar Motheram, Praful Shah and Gopal Krishna. The '762 patent is generally directed to RTU bivalirudin compositions.

17. As discussed below, The Medicines Company is the exclusive licensee of Eagle's interest in the '928 and '762 patents to develop, make, use, sell and market an RTU formulation of bivalirudin.

18. As discussed below, The Medicines Company is, at a minimum, a joint owner of the purported new RTU patent application filed by Defendants and the exclusive licensee of all rights therein.

### **FACTUAL BACKGROUND**

#### **Eagle's 505(b)(2) NDA**

19. The Medicines Company is the owner of New Drug Application ("NDA") N020873, which was approved by the FDA for the manufacture and sale of Angiomax®. Angiomax® is the trade name for bivalirudin, 250 mg/vial, for intravenous injection, and is indicated for, *inter alia*, use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty.

20. On information and belief, Eagle prepared, submitted, and/or filed its 505(b)(2) NDA with the FDA under section 505(b)(2) of the FDCA seeking approval to engage in the

commercial manufacture, use, sale, offer for sale and/or importation of an RTU bivalirudin product for intravenous injection (“Eagle’s Proposed Product”) before the expiration of the ‘928 and/or ‘762 patents.

21. Eagle has publicly announced that its 505(b)(2) NDA “requests FDA approval of Eagle’s RTU bivalirudin product for the treatment of patients: (1) undergoing percutaneous coronary intervention (PCI) with use of glycoprotein IIb/IIIa inhibitor, (2) undergoing PCI with, or at risk of, heparin-induced thrombocytopenia and thrombosis syndrome, or (3) with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA).”

22. Eagle has also stated that it looks “forward to the FDA’s decision on this NDA in March 2016 and, if approved, intend[s] to launch [its] RTU bivalirudin product the following day.”

23. Eagle has further disclosed that “Eagle’s RTU bivalirudin product, which contains the same active ingredient as Angiomax®, is administered as an IV solution at the same dose and rate.”

24. 21 U.S.C. § 355(b)(3) requires that a letter notifying a patent holder and the holder of the NDA for the drug that is claimed by the patent(s) or a use of which is claimed by the patent(s) of the filing of an NDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.”

25. Eagle rejected The Medicines Company’s request for customary confidential access to Eagle’s 505(b)(2) NDA.

26. On January 15, 2016, Eagle by letter advised The Medicines Company that Eagle's 505(b)(2) NDA has a PDUFA action date of March 19, 2016 and that "Eagle's current intention is to promptly launch that product upon approval."

27. Eagle, in its public disclosures, has admitted that Eagle's Proposed Product is subject to the '928 and '762 patents.

28. On November 19, 2015, Eagle's new RTU patent application published, which Eagle has publicly touted that the patent application also covers Eagle's claimed "new" RTU product.

29. A review of the formulation(s) disclosed in the new RTU patent application confirms that Eagle's 505(b)(2) NDA does in fact infringe the '928 and '762 patents.

#### **The Parties' Development Agreement**

30. Several years ago, The Medicines Company engaged -- and paid handsomely -- Defendants to develop an RTU formulation of Angiomax®. The Medicines Company did so based upon Defendants' then claimed expertise in developing RTU formulations.

31. The Medicines Company's development agreement ("Development Agreement") with Defendants made clear that any patents or patent applications arising out of the development program would be jointly owned by The Medicines Company and Eagle.

32. Moreover, the Development Agreement made clear that The Medicines Company would be the exclusive licensee of any such patents or patent applications, even to the exclusion of Defendants.

33. Further, under the Development Agreement, The Medicines Company alone would determine what patent applications, if any, would be filed in connection with the development program.

34. At least during the term of the Development Agreement, Defendants were prohibited from doing any development work around RTU bivalirudin, except on behalf of The Medicines Company.

35. Further, under the Development Agreement, anything conceived or developed during the term of the agreement by Eagle around bivalirudin belongs to The Medicines Company.

36. The Development Agreement expressly recognizes that disputes relating to ownership, filing, prosecution, maintenance, defense or enforcement of patents are to be resolved in courts.

37. Naturally, in furtherance of the development program, The Medicines Company shared its highly sensitive confidential information around Angiomax® in confidence with Defendants.

#### **The Development Program**

38. Based upon the work performed in the development program, two US patents ultimately issued. Each of these patents were assigned to The Medicines Company and Eagle jointly and, in turn, licensed exclusively to The Medicines Company.

39. On the commercial side, however, Defendants were long on promises and short on delivery. To The Medicines Company's disappointment, Defendants failed to develop an RTU bivalirudin product that met The Medicines Company's expectations.

40. Moreover, when The Medicines Company challenged Eagle on its failures, Eagle's only response was to finger-point at The Medicines Company.

41. And then, when finger-pointing did not work out as Eagle planned, Eagle abruptly declared that it was "terminating" the Development Agreement.

**Eagle's Concealed Plan and RTU Patent Application**

42. As it turns out, Eagle's purported "termination" was just a ruse to conceal Defendants' plan to misappropriate for themselves the RTU bivalirudin development program intellectual property and pursue its own patent application for RTU bivalirudin in hopes of launching an RTU bivalirudin product to compete directly with Angiomax.

43. For Eagle, timing was critical. Eagle knew that as long as the Development Agreement was in effect, 1) Eagle was prohibited from developing an RTU bivalirudin product other than for The Medicines Company; and 2) anything conceived or developed by Eagle around bivalirudin can only be exploited by The Medicines Company.

44. Thus, Eagle had to create the illusion of time after Eagle's purported "termination" to claim that Eagle had not misappropriated The Medicines Company's rights in RTU bivalirudin.

45. Eagle's illusion, however, has been unveiled.

46. For example, The Medicines Company has learned that within weeks after Eagle declared its purported “termination” of the development program, Eagle requested and conducted a meeting with the FDA regarding RTU bivalirudin and completed registration batches shortly thereafter -- implausible timeframes for truly new drug formulation development work by any standard.

47. During the same time period, upon information and belief, Eagle filed a patent application directed to RTU bivalirudin technology based on development program intellectual property -- again an incredible “strike of genius” only mere months after Eagle purported to “terminate” its development program with The Medicines Company.

48. Less cautiously (or more brazenly perhaps), Eagle has publicly acknowledged that Eagle’s Proposed Product “was originally subject of a licensing agreement with The Medicines Company” -- a stunning admission that quickly dispels any doubt regarding the true ownership of the new RTU patent application and the RTU bivalirudin technology, and thus any doubt regarding Eagle's substantial exposure in this lawsuit.

49. By any standards or measures, it is implausible within these short timeframes for Eagle to have conceived, invented and developed legitimately on its own -- from scratch -- any novel RTU bivalirudin technology outside the Development Agreement.

50. In fact, upon information and belief, the RTU bivalirudin technology that is the subject of the new RTU patent application was conceived and/or developed during the term of the Development Agreement and/or is otherwise derivative of development program intellectual property.

51. Further, and in any case, Defendants were under a duty to disclose any such development program intellectual property to The Medicines Company. Yet, upon information and belief, Defendants concealed such ideas, conceptions, inventions or other intellectual property from The Medicines Company in an attempt to keep such property for themselves.

52. Further, The Medicines Company was solely empowered to determine whether or not a patent application would be filed and prosecuted in that regard.

53. By filing and prosecuting the new RTU patent application solely in Eagle's name, Defendants have denied and/or misappropriated The Medicines Company's right to joint ownership of the new RTU patent application and its right to control the filing and prosecution of the new RTU patent application.

54. Eagle is actively promoting publicly its 505(b)(2) NDA filing and the filing of the new RTU patent application. In doing so, Eagle is knowingly or at least recklessly giving a false and misleading impression that Eagle owns exclusive rights to the new RTU patent application, even to the exclusion of The Medicines Company.

55. Moreover, in its promotions, Eagle is knowingly or at least recklessly giving a false and misleading impression that its purported rights in the new RTU patent application somehow provide Eagle with a competitive advantage over The Medicines Company, all to the detriment of The Medicines Company.

## **CAUSES OF ACTION**

### **COUNT I** **Infringement of the '928 Patent**

56. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

57. Eagle, by and through its 505(b)(2) NDA, seeks FDA approval for the manufacture, use, sale, offer for sale and/or importation of Eagle's Proposed Product.

58. Eagle has not certified that it does not infringe the '928 patent or that the '928 patent is invalid.

59. Upon information and belief, Eagle has publicly acknowledged that Eagle's 505(b)(2) NDA is subject to and infringes the '928 patent.

60. Upon information and belief, Eagle will commercially manufacture, sell, offer for sale, and/or import Eagle's Proposed Product upon FDA approval, including within this judicial district.

61. The filing of Eagle's 505(b)(2) NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the United States of Eagle's Proposed Product before the expiration of the '928 patent is an act of infringement by Eagle of one or more claims of the '928 patent directly and/or indirectly in a cooperative venture under 35 U.S.C. § 271(e)(2)(A).

62. On information and belief, Eagle's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Eagle's Proposed Product will infringe one or more claims of the '928 patent directly under 35 U.S.C. § 271(a) and/or indirectly under 35 U.S.C. § 271(b) and/or (c).



63. On information and belief, Eagle was aware of the existence of the '928 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '928 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

64. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Eagle is preliminarily and permanently enjoined by this Court.

**COUNT II**  
**Infringement of the '762 Patent**

65. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

66. Eagle, by and through its 505(b)(2) NDA, seeks FDA approval for the manufacture, use, sale, offer for sale and/or importation of Eagle's Proposed Product.

67. Eagle has not certified that it does not infringe the '762 patent or that the '762 patent is invalid.

68. Upon information and belief, Eagle has publicly acknowledged that Eagle's 505(b)(2) NDA is subject to and infringes the '762 patent.

69. Upon information and belief, Eagle will commercially manufacture, sell, offer for sale, and/or import Eagle's Proposed Product upon FDA approval, including within this judicial district.

70. The filing of Eagle's 505(b)(2) NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation into the

United States of Eagle's Proposed Product before the expiration of the '762 patent is an act of infringement by Eagle of one or more claims of the '762 patent directly and/or indirectly in a cooperative venture under 35 U.S.C. § 271(e)(2)(A).

71. Upon information and belief, Eagle's commercial manufacture, use, sale, offer for sale and/or importation into the United States of Eagle's Proposed Product will infringe one or more claims of the '762 patent directly under 35 U.S.C. § 271(a) and/or indirectly under 35 U.S.C. § 271(b) and/or (c).

72. Upon information and belief, Eagle was aware of the existence of the '762 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '762 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

73. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless Eagle is preliminarily and permanently enjoined by this Court.

**COUNT III**  
**Declaratory Judgments Regarding Patent Ownership Rights**

74. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

75. As alleged herein, all intellectual property, including patent rights, developed during the term of the development agreement shall be jointly owned by The Medicines Company and Eagle.

76. As further alleged herein, The Medicines Company is the exclusive licensee of all such patent rights with respect to RTU bivalirudin, even to the exclusion of Defendants.

77. For the reasons alleged herein, upon information and belief, the new RTU patent application (and all patent rights therein) filed by Defendants solely in their own name(s) are: a) at least jointly owned by The Medicines Company and Eagle; b) alternatively, owned exclusively by The Medicines Company; and c) licensed exclusively to The Medicines Company, even to the exclusion of Defendants.

78. Defendants have publicly taken positions that are adverse to The Medicines Company's positions on these issues.

79. Therefore, there exists a dispute between the parties which requires, and over which The Medicines Company has a right to seek, an adjudication by this Court.

80. Consequently, The Medicines Company requests that Court declare that: a) The Medicines Company is, at the very least, a joint owner of the new RTU patent application; b) the exclusive licensee of any patent rights under the new RTU patent application; and c) at the very least, a joint owner of any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company.

81. Further, in light of Defendants' willful, bad faith and intentional acts as alleged herein, The Medicines Company requests that Court declare that The Medicines Company is: a) the sole owner of the new RTU patent application; b) the exclusive licensee of any patent rights under the new RTU patent application; and c) the sole owner of any other development program

intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company.

**COUNT IV**  
**Breach of Contract (Patent Ownership)**

82. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

83. Under the Development Agreement, Defendants agreed that The Medicines Company in consultation with Eagle, shall be solely responsible for the filing, prosecution and maintenance of joint patents regarding development program intellectual property.

84. Upon information and belief, the new RTU patent application covers development program intellectual property. Further, Defendants filed the new RTU patent application without first disclosing its subject matter to The Medicines Company, without the approval by The Medicines Company and without disclosing The Medicines Company as having an ownership interest therein -- each of which is a breach of the Development Agreement.

85. Consequently, The Medicines Company requests that Court declare that Defendants have breached the Development Agreement, and order Defendants to transfer sole and exclusive control of the filing and prosecution of the new RTU patent application and any related patents or patent applications to The Medicines Company.

86. Further, as a result of Defendants' breaches, The Medicines Company has been damaged.

87. Moreover, as a result of Defendants' actions and omissions, The Medicines Company has been, and will continue to be, irreparably harmed unless Defendants, and all persons or entities acting on their behalf, in concert with them or as their agents, are permanently enjoined from filing and prosecuting patent applications regarding development program intellectual property in their own name(s), including the new RTU patent application.

**COUNT V**  
**Conversion**

88. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

89. As detailed above, the Development Agreement recognizes that The Medicines Company has an ownership interest in development program intellectual property, including joint patents.

90. Upon information and belief, Defendants have filed and are prosecuting the new RTU patent application in their own name(s), contrary to and in exclusion of The Medicines Company's ownership and control rights, that covers development program intellectual property.

91. Upon information and belief, The Medicines Company is at least a joint owner in the new RTU patent application, the development program intellectual property set forth in that patent application, and is the sole party entitled to control that patent application.

92. Upon information and belief, Defendants wrongfully converted The Medicines Company's joint ownership rights in the new RTU patent application to their sole property and wrongfully excluded The Medicines Company from its sole right to control the filing and prosecution of the new RTU patent application.

93. As a result of Defendants' conversion, The Medicines Company has been damaged.

94. Moreover, as a result of Defendants' conversion, The Medicines Company has been, and will continue to be, irreparably harmed unless Defendants, and all persons or entities acting on their behalf, in concert with them or as their agents, are permanently enjoined from filing and prosecuting patent applications regarding development program intellectual property in their own name(s), including the new RTU patent application.

**COUNT VI**  
**Misappropriation**

95. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

96. Under the Development Agreement, whereby Defendants agreed that The Medicines Company is entitled to joint ownership of all development program intellectual property and would control exclusively all decisions relating to filing and prosecuting related patent applications.

97. Upon information and belief, Defendants are in possession of development program intellectual property concerning RTU bivalirudin technology that they withheld from The Medicines Company.

98. Upon information and belief, Defendants have filed the new RTU patent application in their own name(s).

99. Defendants, by their actions, have unlawfully misappropriated The Medicines Company's intellectual property rights, its rights in the new RTU patent application, and its right to control exclusively all decisions relating to the filing and prosecution of patent applications relating to development program intellectual property.

100. As a result of Defendants' misappropriation, The Medicines Company has been damaged.

101. Moreover, as a result of Defendants' misappropriation, The Medicines Company has been, and will continue to be, irreparably harmed unless Defendants, and all persons or entities acting on their behalf, in concert with them or as their agents, are permanently enjoined from filing and prosecuting patent applications regarding development program intellectual property in their own name(s), including the new RTU patent application.

**COUNT VII**  
**Unjust Enrichment**

102. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

103. As set forth more fully above, Defendants breached their duties to The Medicines Company and unlawfully converted and misappropriated The Medicines Company property and rights by filing and claiming ownership to the new RTU patent application.

104. On information and belief, Defendants have been and/or will be enriched at The Medicines Company's expense. Any enrichment that Defendants have received and/or will receive from the filing and prosecution of the new RTU patent application is a result of Defendants' breach of their duties and unlawful conversion and misappropriation of The

Medicines Company's property and rights. Accordingly, any such enrichment is unjust and should, in equity and good conscience, be returned to The Medicines Company.

105. As a result of Defendants' unjust enrichment, The Medicines Company has been damaged.

106. Moreover, as a result of Defendants' actions and omissions, The Medicines Company has been, and will continue to be, irreparably harmed unless Defendants, and all persons or entities acting on their behalf, in concert with them or as their agents, are permanently enjoined from filing and prosecuting patent applications regarding development program intellectual property in their own name(s), including the new RTU patent application.

**COUNT VIII**  
**Constructive Trust**

107. The Medicines Company hereby incorporates by reference each of the preceding paragraphs as if fully set forth herein.

108. As set forth more fully above, Defendants breached their duties to The Medicines Company and unlawfully converted and misappropriated The Medicines Company property and rights by filing and claiming ownership to the new RTU patent application. On information and belief, Defendants, by their actions, have been and/or will be unjustly enriched at The Medicines Company's expense.

109. Any unjust enrichment that Defendants have received and/or will receive from its acts is held in trust by Defendants for the benefit of The Medicines Company. The Medicines Company has no adequate remedy at law and will suffer irreparable harm unless a trust is imposed over the new RTU patent application and over any amounts by which Defendants were



unjustly enriched and Defendants, and all persons or entities acting on their behalf, in concert with them or as their agents, are permanently enjoined from filing and prosecuting patent applications regarding development program intellectual property in its own name, including the new RTU patent application.

110. As a result of Defendants' breach of their duties and unlawful conversion and misappropriation of The Medicines Company property and rights, The Medicines Company's ownership interest in the new RTU patent application should be placed and held in trust for the benefit of The Medicines Company.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, The Medicines Company respectfully demands the entry of judgment against Defendants as follows:

(a) Declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of NDA No. 208298 to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of NDA No. 208298 was and is an act of infringement of the '928 patent, and/or '762 patent by Defendants directly and/or indirectly;

(b) Declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of NDA No. 208298 prior to the expiration of the '928 patent, and/or '762 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly;

(c) Ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of NDA No. 208298 shall be no earlier than the last date that the '928 patent and '762 patent expire, including any regulatory extensions;

(d) Preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 271(e)(4)(B), Defendants and all Defendants' officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of NDA No. 208298 until the expiration of the '928 patent and '762 patent, including any regulatory extensions;

(e) Awarding damages or other monetary relief to The Medicines Company, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if any Defendant receives FDA approval and commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of NDA No. 208298 that infringes the '928 patent and '762 patent;

(f) Declaring that infringement of the '928 patent and/or '762 patent is willful if any Defendant receives FDA approval and commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of NDA No. 208298 that infringes the '928 patent and/or '762 patent;

(g) Declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding The Medicines Company its attorneys' fees and costs;

(h) Declaring that The Medicines Company is at least a joint-owner of U.S. Patent Application No. 14/711,359, any patent that may issue therefrom and any other development

program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company;

(i) Declaring that The Medicines Company is the sole owner of U.S. Application No. 14/711,359, any patent that may issue therefrom and any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company;

(j) Declaring that The Medicines Company is the exclusive licensee of all rights in U.S. Application No. 14/711,359, any patent that may issue therefrom and any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company;

(k) Directing Defendants to assign exclusive control over the filing and prosecution of U.S. Application No. 14/711,359, any patent that may issue therefrom and any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company;

(l) Placing in trust for the sole benefit of The Medicines Company U.S. Application No. 14/711,359, any patent that may issue therefrom and any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company;

(m) Enjoining Defendants from filing, prosecuting, transferring or otherwise taking any actions regarding U.S. Application No. 14/711,359, any patent that may issue therefrom and

any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company, anywhere;

(n) Enjoining Defendants from continuing to promote as its own rights in U.S. Application No. 14/711,359, any patent that may issue therefrom and any other development program intellectual property that Defendants are seeking to patent and have otherwise withheld from The Medicines Company, anywhere, and directing Defendants to issue retractions or other forms of corrective advertising to address the false and misleading statements regarding their purported rights in said applications;

(o) Directing Defendants to provide The Medicines Company with a full accounting such that The Medicines Company can properly address and remedy Defendants' unlawful actions as alleged herein;

(p) Awarding The Medicines Company compensatory and punitive damages;

(q) Awarding The Medicines Company interest;

(r) Ordering Defendants to return to The Medicines Company all unjust enrichment they have received and/or will receive at The Medicines Company's expense and/or detriment;

(s) Awarding The Medicines Company all costs and expenses incurred herein, including an award of reasonable attorney's fees; and

(t) Awarding such other and further relief as the Court deems just and proper.

s/ David E. De Lorenzi  
David E. De Lorenzi, Esq.  
Christopher H. Strate, Esq.  
**GIBBONS P.C.**  
One Gateway Center  
Newark, New Jersey 07102  
(973) 596-4500  
(973) 596-0545

*Attorneys for Plaintiff*  
*The Medicines Company*

Dated: February 2, 2016